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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,383	02/05/2002	Marco Thyres	0480-01211	2952

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EXAMINER

OH, TAYLOR V

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,383

Applicant(s)

THYES ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/05 has been entered.

The Status of Claims

Claims 3-8 are pending.

Claims 3-8 have been rejected.

DETAILED ACTION

1. Claims 3-8 are under consideration in this Office Action.

Drawings

2. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

Art Unit: 1625

steps. See MPEP § 2172.01. The omitted step is: 1. how the ethyl 3-dimethylamion-2-phenyl-propionate is converted into the ethyl atropate by eliminating dimethyl amine under specific reaction conditions (i.e. temperature and reagents, time). It is because this step is critical to obtaining a cis/trans mixture of ethyl 2-dimethyl-amino-1-phenyl-3-cyclohexene-1-carboxylate. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1625

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novack (US 3,649,628).

Novack discloses a process for reducing the content of ethyl 3-dimethylamino-2-phenylpropionate in a mixture containing ethyl 2 -dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate, which has been exemplified in the following (see col. 6, lines 20-60) :

Art Unit: 1625

(A) Reaction of crotonaldehyde, dimethylamine and ethyl atropate (atropic acid ethyl ester)

Into a 22-liter three-neck flask, equipped with a stirrer and thermometer, charge 2960 grams (42.3 mols) of anhydrous crotonaldehyde, 2120 ml. of anhydrous benzene, 10.6 grams of phenanthrenequinone, and 2920 grams (21.15 mols) of anhydrous potassium carbonate. Into this mixture, at 5° C., condense 955 grams (21.2 mols) of anhydrous dimethylamine over a two and one-half hour period. Upon completion, stir for 15 minutes and flush the system thoroughly with nitrogen. Add, all at once 3660 grams (18.95 mols) of ethyl atropate (91.2% purity by GLC) and heat to about 75° C. (15 minutes). Remove external heating and allow the reaction temperature to rise to 90° C. and control by external cooling. When the reaction is no longer exothermic, maintain at 90° C. to 95° C. for 2 hours.

Pour the reaction mixture into 21 liters of water contained in a 50-liter three-neck flask equipped with a stirrer and extract with 10.5 liters of benzene. Separate the benzene and discard the aqueous layer. Extract the benzene layer with 2 portions of 1 N hydrochloric acid (22 liters and 3 liters respectively). The benzene layer is discarded. The acid extracts are combined and washed with 4.5 liters of benzene. Separate the benzene layer and discard.

Basify the aqueous with 1.4 liter of 50% aqueous sodium hydroxide. Extract the aqueous with 2 portions of petroleum ether (11.5 liters and 6 liters respectively). Discard the aqueous layer. Combine the petroleum ether extracts and vigorously agitate with 31 liters of 10% aqueous sodium bisulfite for one and one-quarter hours.

Separate the organic layer and extract the aqueous with 4.7 liters of petroleum ether. Discard the aqueous. Combine the petroleum ether extracts and wash twice with 5-liter portions of water. Discard the aqueous. Dry the petroleum ether with magnesium sulfate, filter, and concentrate to totally remove petroleum ether under vacuum (on steam bath, 15 mm.) to a 4135-gram residue (80% of theoretical). Gas liquid chromatography indicates 60% cis isomer, 40% trans isomer, and less than 0.1% of ethyl 2-phenyl-3-dimethylaminopropionate.

The reference also indicates that hydrochloric acid and organic acids such as acetic acid, benzoic acid, citric acid, tartaric acid, etc.(see col. 5, lines 25-28) can be useful in the porcess.

The instant invention , however, differs from the prior art in that the carboxylic acid is used in an amount of from 0.75 to 2.0 equivalent per mole of ethyl 2 – dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate.

Art Unit: 1625

Concerning the molar ratio between the carboxylic acid and ethyl 2 – dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate, the prior art is unspecified. However, the limitation of a process with respect to ranges of molar ratio, pH, time and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. The molar ratio is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to control the molar ratio between the carboxylic acid and ethyl 2 – dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate by a routine experimentation in order to achieve optimum operation of the process.

The Novack prior art expressly teaches that it is possible to reduce the claimed content of ethyl 3-dimethylamino-2-phenylpropionate in the mixture to a less than 0.1 %; furthermore, it has offered guidance that hydrochloric acid and acetic acid are equivalent to each other with respect to their use in the process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to use the acetic acid instead of hydrochloric acid as an alternative during the process. This is because the skilled artisan in the art would expect such a modification to be feasible to the process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Myra V. On
6/21/06